Date: January 22,2002

Subject: Proposed Revision of Lisitings on Malignant Neoplastic Diseases

To: Office of Process and Innovation Management, SSA

From: Laurence Goldstein, MD

The proposed revision of the Neoplastic Listings was published In the Federal Register on November 27, 2001. I wish to offer the following observations and comments.

- Patients with Inflammatory breast cancer (existing listlng 13.09B and new listing 13.10A) have a median survival of appmxlmately 3 years. Patients with bone metastases from breast cancer (exlstlng listlng 13.09D and new llstlng 13.10B) have a median survival of approximately 4 years. The proposed listing revisions appropriately include some new categories with comparable median survivals, these Include stages 3 and 4 cervical cancer, stages 3 and 4 endometrial cancer, and stages Ic – IV ovarian cancer. However, under both the current regulatlons and the proposed revisions, malignancies wlth slmllar outlooks am not designated as listings. These Include primary lymphoma of the CNS (medlan survival of approxlmately 3 years), stages 2 and 3 myeloma (medlan survivals *of* approxlmately 2 & 3 years respectively), and prostate cancer with bone metastases (with involvement of ribs, skull, or long bones, median survival is approximately 2 years; when bony spread is confined to the pelvis or vertebrae, medlan survival is approximately 4 years). It seems appropriate to consider these categorles, as well, for listing status.

- Under the existing regulatlons, non-squamous non-small cell carcinoma with positlve hilar nodes (median survival approximately 3 years) is a listlng (13.13C). Thls llsting has been ellmlnated in the proposed revlslons in the apparent absence of slgnificant treatment advances and significant Improvement in prognosis. The explanation

offered ("... metastases to the hilum can often be surgically excised") is not fully persuasive. For decades, standard surgical procedures have usually excised involved hilar nodes, but this has not altered the unfavorable prognosis. One finds other examples of nodal metastases (stomach, bladder, kidney, melanoma) that continue to be listings notwithstanding apparent resectibility. Since the prognosis for N1 squamous cell carcinomas is the same, this should continue to be a listing.

- In the case of the revisions to the adult hematologic and the childhood neoplastic/hematologic listings, most of the changes a m deletions. The areas of expanded eligibility may be expected to have little impact. In the adult hematologic revisions, criteria were tightened for chronic anemia, sickle cell diseases chronic thrombocytopenia, and chronic granulocytic leukemia. In the childhood hematologic revisions, criteria are more restrictive for hemolytic anemias, sickle cell diseases and chronic thrombocytopenia. In the childhood neoplastic revisions, criteria are more restrictive for non-Hodgkin's lymphoma, chronic granulocytic leukemia, thyroid carcinoma, medulloblastoma, Wilms' tumor, testicular cancer, and germ cell tumors. Although good arguments may be made for these changes, the trend gives rise to concern as to the appropriateness of the balance being struck.

- There is overlap in proposed listings 113.25 (testicular cancer) and 113.26 (gem cell cancer). Testicular cancers are, in fact, often germ cell tumors. If 113.26 is used, a testicular cancer (gonadal germ cell tumor) treated with orchiectomy alone becomes an allowance at the time of nodal or distant recurrence, despite the very good prognosis. Is 113.26 intended for ovarian germ cell tumors and extragonadal germ cell tumors, but not testicular gem cell tumors? There is a proposed childhood listing for extragonadal germ cell tumors (113.26). Might we not also have a comparable adult listing?

- 13.00E(3) could be interpreted as implying that single modality treatment requires us to wait 8 months before adjudicating a case. Taken literally, that would apply to surgical resection of early bowel cancer or radiotherapy of early vocal cord cancer. Perhaps the language of this section could be clarified to allow flexibility on the basis of the facts of the individual case.

- According to 13.00E(3), we "usually" must await the effects of "all" multimodality components before making a decision. These multimodality treatments could apply to a variety of situations. It is usually appropriate to defer cases until surgery after neoadjuvant chemotherapy of breast or bowel cancer. But multimodality treatment also includes adjuvant therapy, which one would not expect to give rise to deferral. For example, in early Hodgkin's Disease treated with chemotherapy and involved

field radiotherapy, wouldn't the demonstration of early treatment response reasonably support a durational denial? The word "often" might be preferable to "usually." Perhaps a sentence could be added indicating that deferral is not necessary if it is clear that the prescribed treatment will achieve its intended effect.

- Chronic lymphocytic leukemia is mentioned only in the preface, not in the listings themselves. This is a potential source of confusion. For clarity, it is suggested that 13.05, 13.05A, and 13.05A2 contain the phrase "and chronic lymphocytic leukemia,

- The decision to delete listings for metastatic carcinoma to bone, liver, and pleura will avoid much confusion. It is thus puzzling that a listing (13.13C) for CNS metastases has been retained. Does this apply to all cases of testicular carcinoma with CNS metastases?

- In proposed listing 13.128 the phrase "or with regional or distant metastases" may be unnecessary. Regional and distant metastases are covered in 13.12A.

- The existing listing for neuroblastoma (113.04) includes recurrent disease as a listing criterion. The proposed 113.21A does not. Is this deletion a deliberate change? It is not specifically addressed in the section that explains the proposed revisions.

Thank you for the opportunity to offer these comments.